

Addressing (Low) Back Pain in the Era of the European Pillar of Social Rights: Assessing Impact and Sharing Good Practices Across Europe

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1. Abstract

The manuscript provides the scientific society and experts involved in pain relief and patient empowerment with a good practice focused on low back pain (LBP). Such best practice is particularly relevant today, taking into account the important advancements in the fight against pain and the new context of the European Pillar of Social Rights. In particular, key principle N.17 on the “Inclusion of people with disabilities” declares that “People with disabilities have the right to income support that ensures living in dignity, services that enable them to participate in the labor market and in society, and a work environment adapted to their needs” [1].

In continuity with its long-term policy on the fight against pain, the Italian NGO Cittadinanzattiva APS [2], through its EU branch Active Citizenship Network [3] (ACN), has become an official Ambassador for the EU Social Pillar, following the invitation by the EU Commission-DG EMPL in 2020, in order to contribute to better implement the European Pillar of Social Rights for people suffering from chronic pain. This article has been written with the hope that the collection and dissemination of

good practices against chronic pain, which ACN has been carried out across Europe for years, as well as the online publication of good practices by experts and committed operators, could be valued in the contest of the European Pillar of Social Rights and contribute to transfer the recent achievement on chronic pain from the European political agenda to the European culture as fast as possible.

2. Keywords: Chronic Pain; Low Back Pain; Good Practices; European Pillar for Social Rights; Citizens’ Engagement; Patients Advocacy Groups (PAGs)

3. Introduction

Non-specific low back pain (LBP) is one of the leading causes of global disability. Low back pain is an epidemic condition affecting almost everyone during the lifetime. It peaks in working adults and represents the primary cause of sick leave and forced early retirement. Low back pain causes 335 million lost working days in the EU every year,

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costing employers and healthcare systems more than €300 billion annually.

Clinical guidelines recommend therapy sessions at physiotherapy centers and home-based exercises. Although the efficacy of this type of therapy is scientifically proven, 70% of patients do not complete the therapy. Studies show that the prime reasons are lack of medical feedback on exercise performance and lack of motivation during home-based therapy.

Patients with low back pain have an urgent need for solutions that provide them with tailored feedback on their therapy and that keep them motivated in order to adhere to the therapy. Patients need to be empowered to be able to self-manage their condition and live a pain-free life.

The European Trade Union Institute (ETUI) [4] defines musculoskeletal disorders (MSDs) as inflammatory and/or degenerative ailments affecting all sectors and all categories of workers. The biggest Europe-wide occupational health survey found 46% of European workers reporting back pain, while 43% had painful shoulder, neck and upper limb muscles.

For instance, back pain has been the most common reason for sick leaves in Germany for years. According to a recent study by the German health insurance company DAK-Gesundheit, the trend continues. In 2019, 21,2% of the sick leave diagnoses were related to back pain and similar disorders. This is slightly more than in the previous year (20,9%), as found by DAK-Gesundheit, after analyzing data from around 2.4 million employed insured persons [5].

More in general, a study conducted by the Global Burden of Disease (2017) found that low back pain is the leading cause of disability in almost all high-income countries as well as central Europe, Eastern Europe, North Africa, the Middle East, and parts of Latin America. Every year, a total of 1 million years

of productive life is lost in the UK because of disability from low back pain; 3 million in the USA; and 300,000 in Australia.

The global burden of disability caused by low back pain has increased by more than 50% since 1990 and is due to increase even further in the coming decades as the population ages.

4. Results and Discussion

With concern to low back pain, Active Citizenship Network, through its EU project “EU Civic Prize on Chronic Pain - Collecting good practices” [6], provided evidence of existing good practices across European countries in terms of struggle against pain. Among them, some are related to low back pain. In particular, the winner for the category “Clinical Practices”, awarded on 6 November 2019 in Bruxelles, is the Good Practice “Rise-uP” [7] by the Center of Interdisciplinary Pain Medicine, Dep. of Neurology, MRI Munich, Technical University of Munich, Germany.

5. Objective

“Patients are the issue; it is all about them!” With this slogan, the Rise-uP project [8] aims to overcome the less structured treatment of acute and subacute unspecific low back pain in Germany. Although evidence has been provided which underlines the insufficient long-term efficacy of the present practice (i.e. not indicated surgery, medication or imaging), these measures still prevail with high costs for the healthcare system. In contrast, evidence-based interventions fostering patients’ empowerment are widely neglected. Furthermore, patients with an increased risk of developing chronic pain are often not identified and treated insufficiently. Rise-uP aims to establish a guidelines-oriented treatment algorithm including telemedicine and mHealth coordinated by the general physician. The cores of the concept are twofold. Firstly, the main intervention is the Kaia App, a multidisciplinary back pain app providing the

pillars of the multimodal pain therapy - physical exercise, psychological elements (mindfulness) and educational content about low back pain - on the patient's mobile device. A daily training program is tailored to the particular patient via an algorithm and the patient is recommended to use the app "as often as possible". Secondly, the risk of developing chronic pain is determined in the beginning of the treatment via a questionnaire (Start Back). Questionnaires regarding pain intensity, functional ability, psychopathological symptoms and life quality are completed by the patient on a tablet on the first appointment with the GP. These data are then transferred to a server and patients with a high risk of developing chronic pain are monitored. Additionally, a pain specialist gets involved via telemedicine from the beginning of the treatment to maximally prevent the development of chronic pain. A shared electronic case report form which also guides the general practitioner through the treatment algorithm provides access to the patients' data to all involved professionals.



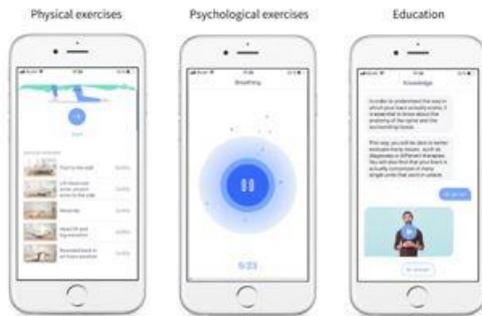
5.1. Outcomes and Impact on Participants:

Questionnaires regarding pain intensity, functional ability, psychopathological symptoms and life quality are completed by the patient on the first appointment with the general physician on a tablet and every 3, 6 and 12 months after inclusion via

email (follow-up). The primary outcome is the pain intensity after 12 months. Secondary outcomes are functional ability, psychopathological symptoms and life quality as well as treatment costs (routine data provided by health insurances). Data of patients in the Rise-uP intervention are compared to a control group receiving regular treatment. In this group, general practitioners are instructed "to treat their patients as they usually do". General practitioners in the control group are not informed about Rise-uP in detail. In addition to the outcomes after 12 months, symptom load is assessed 3 months and 6 months after the study's inclusion to monitor the development of symptoms. All questionnaires are provided via email. In order to unfold the effects of the Rise-uP concept on symptoms, user data of the app and frequency of teleconsultations are analyzed as well. The first results indicate (a) a superiority of the Rise-uP concept after 3 months in all parameters and (b) a substantial relationship between frequency of use of the Kaia App and symptom reduction.

5.2. Resources: Rise-uP is possible thanks to the collaboration of medical, informatic and research experts as well as public German health insurances. The basic structure of the treatment algorithm is oriented to present guidelines. Telemedical and mHealth elements were developed by informatic specialists. The content of the Kaia App was developed by physiotherapists, psychologists and medical doctors. The first studies on the app data independent from the Rise-uP project demonstrate the effectiveness of the app. Study design was developed by statistical and methodological experts. Health insurances provide routine data. In the course of the intervention, general practitioners coordinate the treatment. The project team built a network of about 100 general practitioners in Bavaria (Germany). Medical experts as well as psychologists get involved when needed. The Rise-uP project is funded with 5 Million Euro by the German

Bundesausschuss (G-BA). Altogether a team of more than 25 experts collaborate in this project.



5.3. Factors Enabling the Process:

By unburdening the doctor's staff through a bottom up approach, patients' inclusion substantially increased.

5.4. Development of the Good Practice: The skeleton of the treatment algorithm are the German national guidelines for the treatment of unspecific low back pain ("Nationale Versorgungsleitlinien Kreuzschmerz") which fosters patients' empowerment and also recommends determining the risk of development of chronic pain. The treatment is in line with all other national guidelines around the world. In the Rise-uP project the guidelines are digitized by the electronic case report which also guides the general practitioner through the course of the treatment. Furthermore, the Kaia App represents a main intervention: it was technically developed by informatics, the content was provided by medical experts, and patients' needs were referred to by different stakeholders.

5.5. Stakeholders Involvement: Civic organisations and PAGs: SchmerzLOS (Self-help group). Healthcare organisations: AOK Bayern, Barmer GEK, DAK (public German health insurances).

University: Technical University of Munich, MRI Munich, Center of Interdisciplinary Pain Medicine.

Health Professionals:

- Prof. Dr. Thomas R. Toelle (Neurologist and Psychologist, pain specialist) including his team

of medical doctors, psychologists and physiotherapists at the Center of Interdisciplinary Pain Medicine, MRI Munich;

- Prof. Dr. Christine Schiessl (Anaesthetist, pain specialist) including her team of medical doctors at Algesiologikum Munich - about 100 general physicians in Germany recruiting patients and applying the good practice.

IT experts:

- Kaia Health Software GmbH (Munich, Germany): Technical development of Kaia App;

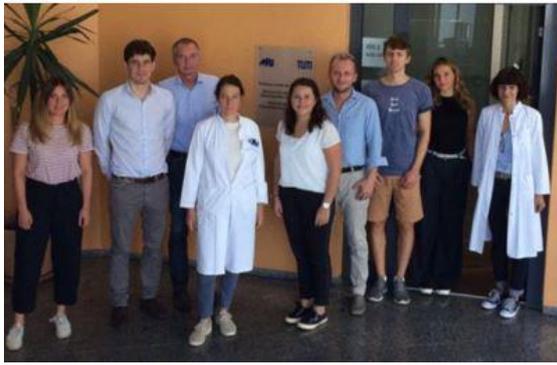
- StatConsult (Magdeburg, Germany): Technical development and maintenance of the electronic case report form Pain clinic;

- Algesiologikum (Munich, Germany): Teleconsultation Bayerische Telemedallianz BTA (Ingolstadt, Germany);

- Organisation and Recruiting INAV (Berlin, Germany): Evaluation.

Janosch Priebe, Senior research fellow at the Technical University of Munich's Center of Interdisciplinary Pain Medicine, Germany, representing the winner of the European Civic Prize on Chronic Pain, Second Edition for the category 'Clinical Practices' with 'Rise-uP' (Award Ceremony within SIP Symposium, Brussels, 6 November 2019). Dr. Janosch A. Priebe, psychologist and neuroscientist, is in charge of the operative management of the research activities in the Rise-uP project, run and supervised by the project leader Prof. Dr. Thomas R Toelle.





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6. Conclusion

6.1. Comment of the Jury Panel

An independent jury panel composed of international experts in chronic pain (academics, healthcare professionals and providers' organisations, civic and patients' associations, etc.) has awarded the Rise-uP project for the following motives: "an outstanding project, describing a comprehensive collaboration between health care professionals (specialist and general physicians), health care organisations, technical organisations and patients. It is a good use of modern innovative technology applied to a common, but potentially disabling condition. It provides a structured scientific thoughtful approach using validated questionnaires and national guidelines. Patients are at the centre of this project, with a system for identifying and progressing those who have specific needs. This is an excellent project built on a broad coalition with a firm clearly clarified goal". "Rise Up proves to us the possibility of creating synergy and trust between sufferers and careers through new technology. The importance of the project and the doors opened are an amazing example to follow".

"The relevant aspect is the attention to the risk of developing chronic pain and the early selection of the patients. The strength point is also in the involvement of general practitioners".

Rise-up has deserved such award and flattering judgement for well satisfying the following criteria, which are essential to recognize a good practice from a citizen perspective [9].



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6.2. Reproducibility: (Transfer possibilities and application in places and situations other than those in which it was made): Rise-uP provides a standardized treatment algorithm which can be applied by any practitioner around the world. Patients are assigned a specific treatment after determining the risk of developing chronic pain. The electronic case report form also comprises a navigator guiding the practitioner through the treatment process which facilitates compliance to the treatment algorithm. The main intervention, i.e. the Kaia App, is available on both Google Play and iOS AppStore. In the Rise-uP project, no costs for the Kaia App are incurred for patients.

6.3. Innovativeness: (The ability to generate new and creative solutions to improve the quality of services and the protection of citizens' rights): The telemedical consultation and electronic health approach is per se an innovative element in the Rise-uP project. Yet, three particular elements should be highlighted:

- The Kaia App: Although mHealth solutions are finding their way into the medical reality, the implementation of an app in a treatment

algorithm in which professionals are involved is to our best knowledge unique in the RiseuP project;

- **Teleconsultation:** Patients with high risk of developing chronic pain are discussed by the general practitioner and a pain specialist in a teleconsultation. Professionals are connected by a video conference system with secure connection (Cisco);
- **Electronic case report form:** The electronic case report form provides access to patients' data for the involved professionals and at the same time guides the general practitioner through the treatment algorithm.

6.4. Added Value: (As a positive and tangible impact, for instance, on users' rights and the promotion of civic participation): We consider the features below described as especially valuable both for patients and professionals.

- **Guideline oriented treatment** fostering patients' empowerment;
- **Treatment coordinated** by the general practitioner;
- **Access to pain specialists** if needed;
- **Decreased costs** for the health system by preventing unnecessary expensive; measures like imaging or surgery.

6.5. Appropriateness: (A practice enabling an efficient and effective management of an issue): Guideline-oriented treatment ensures appropriate intervention. The key element (multimodal pain therapy) is provided independently from time and space via the Kaia App on patients' mobile device. One further gain is the close collaboration between different specialists which is especially valuable for patients with high risk of developing chronic pain. After a first trial, the pool of researchers has drawn lessons and messages both specific for the advancement of the project and more general. In particular:

6.6. Lessons Learned: The course of Rise-uP has

been quite instructive. In a nutshell: The patients are very openminded and interested in electronic and digital health elements, especially in the Kaia App. In contrast, physicians in Germany seem to be rather skeptical. This is also expected in other countries around the world. One reason might be the perceived threatened autonomy which may result from the guideline-oriented treatment algorithm. Furthermore, physicians seem to be afraid of extra effort for the practice team. In order to address the latter issue, a bottom-up approach of recruitment was introduced to maximally release physicians from organizational issues. Since this approach has been applied, physicians are much less skeptical about Rise-uP. As a next step, after the final evaluation in 2020 (end of observational period), the team aim to introduce Rise-uP as a regular intervention for low back pain into the German health system.

6.7. Key Takeaways: Telemedicine and mobile health solutions are promising tools to provide guideline-oriented treatments independent from time and space and connect different medical professionals. The first analyses of the collected data show superiority of the Rise-uP concept compared to regular treatment (publication of results in revision). Furthermore, patients are openminded towards digital health while physicians should be relieved from unnecessary effort.

6.8. The Key Role of the Civil Society: As for us, we strongly believe that good practices represent a small but significant indicator of the health status of our healthcare system, which has long been under pressure due to the need for economic sustainability and the population's high expectations. As health is a common good, its protection should be the shared denominator connecting the many stakeholders involved in the health sector. This also applies to the fight against every form of inequality in access to therapies and to the guarantee of quality standards.

The area of pain is no exception: reducing inequalities to allow a better quality of life for people suffering from chronic pain is the challenge we will face in the coming years. The hope is that the European Pillar of Social Rights could represent the “incubator” for a better and increased access to pain management, starting from a more efficient share of knowhow at European level.

Accordingly, Active Citizenship Network, through the III^o Edition of the European level “EU Civic Prize on Chronic Pain - Collection of good practices” [10], will continue to identify, collect, and disseminate good practices regarding the fight against pain [11] and a better quality of life. This will allow us to keep expanding the “agora” of operators of good practices on pain [12], encouraging the exchange of experiences among health professionals, healthcare providers, Institutions, civic associations, and patient advocacy groups. Overall, the commitment of Active Citizenship Network can be translated as working towards the respect of the patients' right to avoid unnecessary suffering and pain. A commitment that recognizes the key role of the civic society as a whole, totally in line with the message spread in occasion of the above mentioned Informal Council of EU Health Ministers, 2014: "It is important to remember the contribution of non-profit associations toward the development and growth of the palliative culture; and the promotion of initiatives to strengthen and support civic organizations in their work to help patients suffering from pain and patients requiring palliative care. It is vital that patients are of their rights and able to make informed choices” [13].



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